

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-21, 23-30, 32-42, and 45, drawn to a method of making a composite drug containing particle.

Group II, claims 22, 31, 43-44, and 46, drawn to a method of using a composite drug-containing particle.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: their common technical feature is not novel. The common technical feature of each group is a method of producing a drug containing particle by applying pressure and shearing forces to at least two powders, where at least one powder is a drug. Specifically, Ishizaka et al. (US Patent No. 5,336,271) teach a method of making a composite drug particle where a core particle and a crystalline organic compound (drug) are formed together by mechanical impact (pressure) in a high velocity gas stream (see column 2 lines 17-26 and column 4 lines 1-5). Further description of the process by Ishizaka et al. teaches that the powder particle mixture is subjected to mechanical impact as it impacts a rotating member of the taught apparatus, thereby imparting a shearing force (see column 6 lines 3-24). Thus since, this method is known in the art, this technical feature cannot be deemed as special.

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Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

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Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Caralynne Helm whose telephone number is 571-270-3506. The examiner can normally be reached on Monday through Thursday 8-4 (EDT).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel or Cecilia Tsang can be reached on 571-272-0718 or 571-272-0563, respectively. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Caralynne Helm
Examiner
Art Unit 4173

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/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614